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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,420	06/25/2004	Robert K. Kobos	MD1086USPCT	9305

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J Kenneth Joung
Qualicon Inc
Legal Patents
Wilmington, DE 19898

EXAMINER	
CALAMITA, HEATHER	
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1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,420	KOBOS ET AL.	
	Examiner	Art Unit	
	HEATHER G. CALAMITA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims rejected under 35 U.S.C. 102(b) as being anticipated by Biavati et al. (Current Microbiology, 1992).

With regard to claim 1, Biavati et al. teach a process for preparing a processed sample liquid solution for electrophoresis, comprising the steps of:

(a) treating a sample comprising a cell suspension in a non-shearing manner to produce a processed sample liquid solution comprising a mixture of DNA fragments extracted from said cell suspension, wherein at least one of said DNA fragments is greater than 200 kilobase pairs; [see p. 285 under *DNA isolation*, where Biavati et al. teach isolating DNA and see p. 286 under *Restriction endonuclease digestion*, where Biaviati et al. teach subsequently cutting the DNA with restriction endonuclease where at least one of the DNA fragments is larger than 200 kilobases (see Figure 1 for DNA fragment sizes)]

(b) transferring said processed sample liquid solution in a non-shearing manner directly to an electrophoresis medium for conducting electrophoresis (see Figure 1, where the restriction cut DNA was run on an agarose gel).

With regard to claims 2 and 16, Biavati et al. teach the cell suspension comprises one or more cells suspended in a lysis buffer (see p. 285 under *DNA isolation*, where Biavati et al. teach Tris is the lysis buffer).

With regard to claims 3 and 17, Biavati et al. teach the cell suspension is a bacterial cell suspension (see p. 285 under *Materials and Methods*, where Biavati et al. teach the cells used were bacterial).

With regard to claims 4 and 25, Biavati et al. teach treating comprises subjecting the cell suspension to lysis, deproteinization and digestion (see p. 285 under *DNA isolation*, where Biavati et al. teach lysis and deproteinization and see p. 286 under *Restriction endonuclease digestion*, where Biaviati et al. teach subsequently cutting the DNA with restriction endonuclease).

With regard to claims 6 and 27, Biavati et al. teach digestion comprises treatment with a restriction enzyme (see p. 286 under *Restriction endonuclease digestion*, where Biaviati et al. teach subsequently cutting the DNA with restriction endonuclease).

With regard to claims 7 and 28, Biavati et al. teach the restriction enzyme is XbaI (see p. 287 col. 1, where Biavati et al. lists the restriction enzymes used).

With regard to claims 8 and 18, Biavati et al. teach the DNA fragments are 50 kilobase pairs to 1000 kilobase pairs (see p. 287 Figure 1 where Biavati et al. teaches the size of the DNA fragments).

With regard to claims 9-11and 19-21, Biavati et al. teach the process is automated [see p. 285 under *DNA isolation*, where Biavati et al. teach isolating DNA and see p. 286 under *Restriction endonuclease digestion*, where Biaviati et al. teach subsequently cutting the DNA with restriction endonuclease where at least one of the DNA fragments is larger than 200 kilobases (see Figure 1 for DNA fragment sizes) and (see Figure 1, where the restriction cut DNA was run on an agarose gel)].

With regard to claim 12, Biavati et al. teach the electrophoresis medium is an electrophoresis gel (see Figure 1 which is an agarose gel).

With regard to claim 13, Biavati et al. teach the electrophoresis medium is a well of an electrophoresis gel (see Figure 1 which is an agarose gel and the DNA fragments were loaded into each well).

With regard to claim 14, Biavati et al. teach the electrophoresis medium is a viscous sieving solution (see Figure 1 which is an agarose gel. This is a 0.8 % gel which when warmed is a viscous sieving solution).

With regard to claim 15, Biavati et al. teach a process for separating a mixture of DNA fragments extracted from a cell suspension comprising

(a) treating a sample comprising a cell suspension in a non-shearing manner to produce a processed sample liquid solution comprising a mixture of DNA fragments extracted from said cell suspension, wherein at least one of said DNA fragments is greater than 200 kilobase pairs[see p. 285 under *DNA isolation*, where Biavati et al. teach isolating DNA and see p. 286 under *Restriction endonuclease digestion*, where Biaviati et al. teach subsequently cutting the DNA with restriction endonuclease where at least one of the DNA fragments is larger than 200 kilobases (see Figure 1 for DNA fragment sizes)]; and

(b) transferring said processed sample liquid solution in a non-shearing manner directly to an electrophoresis medium for conducting electrophoresis (see Figure 1, where the restriction cut DNA was run on an agarose gel).

(c) separating the mixture of DNA fragments by conducting electrophoresis (see Figure 1, where the DNA was separated on an agarose gel).

With regard to claim 23, Biavati et al. teach the processed sample liquid solution is transferred to a well of the electrophoresis medium (see Figure 1 which is an agarose gel and the DNA fragments were loaded into each well).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biavati et al. (Current Microbiology, 1992) in view of Keating et al. (USPN 5,182,242).

The teachings of Biavati et al. are described above.

Biavati et al. do not teach using achromopeptidase for lysis and deproteinization.

Keating et al. teach using achromopeptdase for lysis and deproteinization (see the abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use achromopeptidase as taught by Keating et al. in the method of isolating DNA as taught by Biavati et al. in order to effectively lyse cells. Keating et al. teach achromopeptidase is an efficient way to lyse bacteria. Keating et al. teach minimal effort and little instrumentation is necessary and that this method of lysis requires only one step and is expedient as compared to prior methods (see the abstract). An ordinary practitioner would have been motivated to use achromopeptidase as taught by Keating et al. in the method of isolating DNA as taught by Biavati et al. in order to effectively, expediently and efficiently lyse bacterial cells.

Allowable Subject Matter

3. Claims 22 and 24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The prior does not teach or suggest isolating and restriction cutting of the DNA without first encapsulating the cells in low melting temperature agarose plugs.

Summary

4. No claims were allowable.

Correspondence

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Heather G. Calamita, Ph.D./
Examiner, Art Unit 1637